

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

October 1, 2004

MEMORANDUM:

Efficacy Review EPA Reg. No. 63761-I
DP Barcode 307221 *Ultra Disinfectant Cleaner Solution 1*

From: Nancy Whyte, Efficacy Team Leader (Acting)
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Nancy Whyte
October 1, 2004

To: Marshall Swindell/Tony Kish
RM Team 33
Regulatory Management Branch I
Antimicrobials Division (7510C)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Sterilex Corporation
11409 Cronhill Drive, Suite L
Owings Mill, MD 21117

Formulation Label:

% by wt.

Active Ingredient(s)

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5%, 5% C ₁₂) dimethyl benzyl ammonium chloride.....	3.00%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chloride.....	3.00%
Hydrogen peroxide.....	6.30%
Other ingredients.....	87.70%
Total	100.00%

I. Background:

This submission from the registrant is in answer to Agency comments contained in its letter of response, dated November 3, 2002, to a request for registration of this one-step

disinfectant cleaner product. The product has two parts, a disinfectant cleaner (Solution 1) and an activator (Solution 2). The submission package from the registrant contained the following documents—an eleven page point-by-point rebuttal of Agency findings, a three page copy of the original product chemistry review and a nine page copy of the original efficacy review from the Agency, a written statement from Karen Ramm, ATS Labs, verifying the preparation of the combination product that was used in the testing of the confirmatory data conducted at ATS Labs in June, July, and August 2002, and copies of the efficacy testing reports (MRIDs No. 460335-02, -03, and -04). The letter from the registrant addressed product chemistry, acute toxicology, and efficacy deficiencies, but only those issues related to product efficacy are addressed in this review.

II. Comments and Recommendations:

1. A comparison of the chemical formulations of the product from which the original efficacy data were ^{submitted} cited to support a disinfectant label claim, and this product verifies the assertion of the registrant that the two are the same. Therefore, the original ^{submitted} cited efficacy data is valid, and is acceptable to support the use of confirmatory data submitted to add additional organisms to the label.
2. The statement from Karen Ramm, ATS Labs, regarding the preparation of the test product used to generate efficacy data is acceptable and also supports the label claims made.
3. An organic soil load was included in the efficacy testing done to support label claims. The comments in the initial efficacy review concerning this are without merit and are disregarded.
4. The label directions for preparation of the use dilution product have been amended to show the correct amount of concentrated product that is used.
5. The initial efficacy review conducted in October 2003 (Page 8, Item No. 2, final three sentences) noted that the efficacy testing was conducted against *Escherichia coli* O157:H7, not *Escherichia coli* and a correction of this error was required. The two organisms are not the same. This label error has not been corrected on the current label enclosed in the data package. The correct designation of this organism must be listed on the label.